Regulatory Services in China

Regulatory Affairs Services Provider in China

The pharmaceutical market in China is the second largest globally, driven by broader access to new drugs, evolving regulations, and a growing societal demand for medicinal products. Key regulatory bodies including the National Medical Products Administration (NMPA), the National Health Commission (NHC), and the Ministry of Human Resources and Social Security (MOHRSS) oversee drugs, medical devices, and traditional medicines.

The NMPA is structured into departments with distinct roles in pharmaceutical regulatory services in China. Its Department of Drug Regulation enforces Good Manufacturing Practice (GMP) in pharmaceutical manufacturing, conducts site inspections, manages pharmacovigilance activities like adverse reaction monitoring, and ensures compliance with regulations and laws. Similarly, the Department of Medical Device Regulation enforces GMP for medical devices , but medical regulatory services in China face increasing registration challenges, including stringent requirements and language barriers that complicate market entry for international manufacturers.

Why choose DDReg for Regulatory Services in China?

As a top-tier provider among regulatory affairs consulting firms in China, DDReg offers comprehensive support and tailored strategies throughout all regulatory phases. We continuously monitor the latest NMPA regulatory services in China requirements to ensure high-quality, timely submissions. Our services include robust safety measures, proactive risk management , and collaboration with specialists to streamline product launches, regulatory filings, and market authorizations.

Our Regulatory Consulting Services In China Portfolio Covers

- NMPA Regulatory Affairs Consulting
- Regulatory Strategies and Expert Views
- Regulatory Due Diligence
- Gap Analysis and Remediation
- New Product Authorizations
- Post Approval Life Cycle Management
- CMC Advisory
- API/DMF
- eCTD Publishing and Submission Services
- ANDA and MA Holding

Country Specific Services

- Regulatory
- Pharmacovigilance
- Labeling
- IPR Support
- Clinical Trial Regulatory
- Medical Devices regulatory services

Our Regulatory Affairs Consulting Services in China portfolio covers:

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Regulatory Strategies

The pharmaceutical industry operates under stringent regulations to ensure the safety,... efficacy, and quality...

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New Product Marketing Authorizations

Navigating marketing authorization is a complex and time-sensitive process. Every...

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Gap Analysis and Remediation

In the highly regulated pharmaceutical industry, maintaining compliance is critical...

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Regulatory Due Diligence

Regulatory issues arise unexpectedly and can create significant strain on a company's...

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API & DMF services

Drug Master Files (DMFs) contain confidential and detailed information regarding API...

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CMC Advisory

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Post Approval Life Cycle Management

Maximize product value with expert pharma lifecycle management. Our dedicated tea...

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Certification Services

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ANDA and MA Holder Services

Our comprehensive services support both Abbreviated New Drug Applications (ANDA) and...

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